

## DETAILED ACTION

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. Previous rejections and other issues not mentioned below are withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,5-11,19,25,26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1,11,25 and 26 specifically recite "release controlling material" which appears to be new matter.

In claim 8 recites "extended release layer further comprises." There appears to be no description of a *extended release layer further comprising* any ingredient.

In claim 9 recites that *a pH modifier is selected from sodium bicarbonate, hydrochloric acid, citric acid, malic acid, and tartaric acid.* No where in the specification does a pH modifier appears to be specifically defined as being sodium bicarbonate, hydrochloric acid, citric acid, malic acid, and tartaric acid. Specified compounds appear to be defined as release modifiers.

In claim 10 release modifiers being defined as fats, fatty acids and transesterification products of fats and fatty acids with polyols appear to be new matter.

In claim 19 excipients being defined as diluents, binders, wetting agents, and disinegrants appear to be new matter.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,5-11,19,25,26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31,,39-42 of copending Application No. 11/988860. Although the conflicting claims are not identical, they are not patentably distinct from each other because USAN '860 independent claim makes claim to a dosage form comprising nimesulide treated with a release controlling polymer. The dependent claims recite that the dosage can have an extended release layer and an immediate release layer and the dosage can be administered as a once day dosage. The dependent claim recite that nimesulide is micronized. The instant independent claim makes claim to a once a day tablet having a fast release layer and an extended release layer which comprises micronized nimesulide, and a release controlling material. Note USAN '860 claims differ in scope from the claims in the instant application. However, USAN '860 claims recite all the limitations recited in the claims of the instant application. Thus, the claims in USAN '860 make instant claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/  
Primary Examiner, Art Unit 1616